

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

NINETEENTH CONGRESS
First Regular Session

HOUSE BILL NO. 4004



Introduced by **HON. LUIS RAYMUND "LRAY" F. VILLAFUERTE, JR.,
HON. MIGUEL LUIS R. VILLAFUERTE, HON. TSUYOSHI ANTHONY G.
HORIBATA AND HON. NICOLAS "NICK" C. ENCISO VIII**

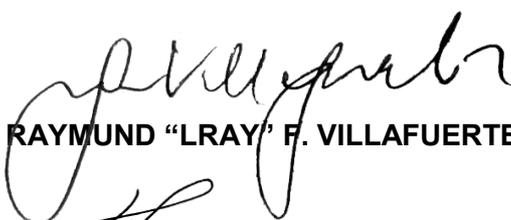
EXPLANATORY NOTE

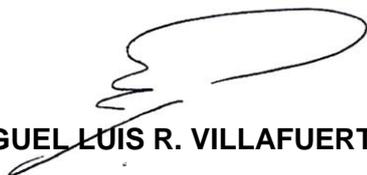
The proposed measure seeks to reform the national policy on organ donation and transplantation from the "opt-in" model currently in force to an "opt-out" model that is more reciprocally altruistic and more responsive to societal realities.

The "opt-in" donation system means that only those who express consent are considered as donors. Meanwhile, the "opt-out" donation model advocated herein treats everyone as a potential donor unless they specifically objected to it. Both models grant individuals or their next of kin power to determine what happens to their cadaveric organs: the difference between the two is the "default" treatment of someone who has expressed no wish either way. As a result, the opt-out model could significantly increase the donation rates as there would be more organs available for patients whose lives depend on an urgent organ transplant.

The bill also proposes a hierarchy of potential organ recipients. For instance, a person who has not registered any objection at any given time with the Department of Health Philippine Network for Organ Sharing (DOH-PhilNOS) in respect of any organ shall be prioritized; a person who has registered his objection with the DOH-PhilNOS, in respect of any organ, but who has withdrawn such objection shall have priority over a person who has registered such objection; and a person who has registered his objection with the DOH-PhilNOS shall be given least priority. This is in line with the ultimate aim of the law to encourage everyone to be organ donors so other people could have a better chance at a new life.

In consideration of the foregoing premises, the passage of this bill is humbly sought.


LUIS RAYMUND "LRAY" F. VILLAFUERTE, JR.


MIGUEL LUIS R. VILLAFUERTE


TSUYOSHI ANTHONY G. HORIBATA


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AN ACT
PROVIDING FOR AN “OPT-OUT” SYSTEM OF ORGAN AND TISSUE
DONATION, PROMOTING THE RIGHT TO HEALTH, PROVIDING PENALTIES
THEREFOR, AND FOR OTHER PURPOSES

*Be it enacted by the Senate and the House of Representatives of the Philippines in
Congress assembled:*

SECTION 1. *Short Title.* – This Act shall be known as the “*Organ and Tissue
Donation Act.*”

SECTION 2. *Coverage.* – This Act shall cover all government and private hospitals,
health facilities, organ and tissue retrieval organizations, medical and allied medical
practitioners or professionals, foundations and non-government organizations that
are involved in organ and tissue donation from deceased donors for transplantation.

SECTION 3. *Definitions.* – For purposes of this Act, the following terms shall be
defined as follows:

- a. Allocation – The assignment of human tissues and organs to a transplant
candidate, based on a set of rules.
- b. Brain Death Criteria – A set of standards, guidelines, or rules that determine
and diagnose brain death by neurological criteria as determined by the
Philippine Neurological Association (PNA).

- c. Clinical Donor Coordinator (CDC) – A healthcare professional who shall be designated to coordinate with the donor family and hospital in order to facilitate a donation and proper transport of donated organs or tissues.
- d. Clinical Transplant Coordinator (CTC) – A designated and trained healthcare professional that takes the central role and acts as liaison between the referring hospital and members of the retrieval and transport teams. He/ she shall have the responsibility of coordinating the transplant candidate's evaluation, management, and follow-up care.
- e. Death – The irreversible cessation of circulatory and respiratory functions or the irreversible cessation of all functions of the entire brain, including the brain stem.
 - 1) Brain Death – The irreversible cessation of cerebral and brain stem function; characterized by absence of electrical activity in the brain, blood flow to the brain, and brain function as determined by clinical assessment of responses. A brain dead person is dead, although his or her cardiopulmonary functioning may be artificially maintained for some time.
 - 2) Cardiac Death – A death resulting from the irreversible cessation of circulatory and respiratory function.
- f. Deceased – A decedent or dead person, includes stillborn infant or fetus.
- g. Department of Health – Philippine Network for Organ Sharing (PhilNOS). – the implementing office of the national organ donation and transplantation program of the DOH, which oversees and facilitates organ and tissue donation and transplantation involving deceased donors in the country. It shall serve as the central coordinating body to ensure that all organs and tissues from deceased donors are allocated according to established criteria.
- h. Donor – A Deceased human being who is a source of organs and/or tissues for the purpose of transplantation.
- i. Eye Bank Technician – A board-eligible or board-certified nurse or medical technologist who underwent training in the science of eye banking which is conducted by an organization duly-accredited by the DOH. Provided that, the training is in accordance with accepted international standards of eye banking and shall include, but not limited to, retrieval, processing, storage, and distribution of eye tissue.

- j. Hospital – A facility devoted primarily to the diagnosis, treatment, and care of individuals suffering from illness, disease, injury, or deformity, or in need of surgical, obstetrical or other medical and nursing care. It shall also be construed as any institution, building or place where there are facilities and personnel for the aforementioned purposes.
- k. Medical Practitioner – Any physician, dentist, nurse, pharmacist, or paramedical or other supporting personnel (including medical and dental technicians, nursing assistants, and therapists).
- l. Organ – A differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularization and capacity to develop physiological functions with an important level of autonomy.
- m. Organ and Tissue Retrieval Organization (OTRO) – A hospital-based organization accredited by the DOH created for the purpose of detecting, identifying, and evaluating potential organ and tissue donors, and recovering such from deceased donors for individuals needing transplantation. OTROs, in coordination with the CDC and CTC, shall serve as the vital link between the donor and the recipient. Their responsibilities include brain, death certification, donor maintenance, and retrieval, preservation, and transport of organs and/or tissues for transplantation.
- n. Organ and Tissue Retrieval Team (OTRT) – A group made up of highly-skilled healthcare professionals led by a surgeon who is competent to safely lead the retrieval of organs and/or tissues for transplantation.
- o. Philippine Organ Donor and Recipient Registry System (PODRRS) – A national computerized and strictly confidential database of all organ transplant candidates, recipients, organ donors, and transplants performed in the Philippines. The system shall also contain the list of individuals who chose and expressed to opt-out from donating organs and/or tissue, as provided in this Act.
- p. Physician – A medical practitioner who is authorized to practice medicine under the laws of the Republic of the Philippines.
- q. Potential Multiple Organ Donor (PMOD) – Any patient who will imminently become brain dead or who currently meets the criteria for brain death who may donate more than one organ and/ or tissue(s).

- r. Procurement – A process that includes donor identification, evaluation, obtaining consent for donation, donor maintenance, and retrieval of organs and/or tissues.
- s. Recipient – A patient to whom human organs and/or tissues are transplanted.
- t. Referring Hospital (RH) – A hospital that identifies and refers potential donors to OTPOs; or to the appropriate Tissue Bank. RHs are required to refer and report potential organ donors to the DOH-PhilNOS.
- u. Tissue – All constituent parts of the human body formed by cells.
- v. Tissue Bank – A hospital unit where activities of processing, preservation, storage, and distribution of human tissues are undertaken. It may also be responsible for procurement of testing tissues.
- w. Transplantation – The transfer (engraftment) of human cells, tissues, or organs from a donor to a recipient with the aim of restoring function/s in the body.
- x. Transplant Candidate – A patient diagnosed to have end-stage organ disease that is qualified to undergo an organ and/or tissue transplant procedure.
- y. Transplant Facility (TF) – A hospital accredited by the DOH to perform organ and/or tissue transplantation.

SECTION 4. *Determination and Declaration of Death.* – A person shall be determined and declared dead if:

- 1) In the opinion of the consulting physician, in concurrence with the attending physician, on the basis of acceptable standards of medical practice, there is an irreversible cessation of all brain functions; and considering the absence of such functions, further attempts at resuscitation or continued supportive maintenance would not be successful in restoring such natural functions. In this case, death shall be deemed to have occurred at the time when these conditions first appeared; or
- 2) In the opinion of the attending physician, based on the acceptable standards of medical practice, there is an absence of natural respiratory and cardiac functions and, attempts are resuscitation would not be successful in restoring those functions. In this case, death shall be deemed to have occurred at the time the functions ceased.

Provided that, the death in person in Sec. 3 hereof shall be determined in accordance with the Brain Death Criteria provided by the PNA, by which brain death shall be declared by two (2) different physicians who are both not part of the transplant team. The physicians are preferably, but not limited to, a neurologist, neurosurgeon, internist, or anaesthesiologist who shall determine and establish brain death based on existing guidelines. The death shall be recorded in the patient's medical record.

SECTION 5. *Establishment of Organ and Tissue Retrieval Organizations (OTROs)*. – The DOH, in coordination with the DOH-PhilNOS, shall accredit and ensure the establishment of OTROs in tertiary hospitals, government and private, as part of the national organ and tissue procurement network.

The OTROs shall establish affiliations with facilities/ institutions that provide ancillary/ support services such as, but not limited to, laboratory diagnostic capability in virology, tissue typing, imaging facility, to include at least an ultrasound machine with Doppler capability, and ambulance services for donor/s, organ/s, and tissue/s transport.

Provided that, each OTRO shall have an Organ Retrieval Team whose members are licensed and board-certified surgical and medical experts. Provided that, collaborations with other retrieval teams of other transplant facilities without an OTRO can be entertained on a case-by-case basis.

Each OTRO shall be mandated to serve its designated Donor Service Area (DSA) which shall be determined by DOH and DOH-PhilNOS, through population-based designation, in coordination with the Philippine Statistics Authority (PSA).

All Tertiary Hospitals and Trauma Centers, with or without OTROs, shall be required to have CDC and CTC in order to optimize the identification and referral of donors and/or PMODs.

SECTION 6. *Retrieval of Organs and Tissue After Death*. – The designated medical practitioner of a hospital may, subject to and in accordance with this Act,

authorize, in writing, the removal of any organ and/or tissue of a dead person unless he/she has opted-out to organ and tissue donation, as confirmed by DOH-PhilNOS through the PODRRS.

Organ procurement may be performed in any hospital provided that is well-equipped and capable of performing such operation while tissue procurement shall be performed by the appropriate Tissue Bank, as accredited by the DOH.

Provided that, for possible medicolegal cases and unidentified dead individuals, no procurement of organ and/or tissue shall be performed and the OTRO shall immediately communicate and inform the Medicolegal Division and Crime Laboratory of the Philippine National Police (PNP) and/or National Bureau of Investigation (NBI).

Moreover, no authority shall be given for the removal of organs and/or tissues from the body of the deceased if:

- 1) During his/her lifetime, he/she has registered an objection to organ and/or tissue donation, as provided in this Act, after his/her death;
- 2) He/she is not a citizen of the Philippines. Provided that, Filipinos who have lost their citizenship and obtained citizenship in another country, and are residents in the Philippines, may also be given authority to donate their organs to a living related transplant recipient, in accordance with the Opt-In System provided in Section 8 hereof; unless with explicit consent to donate;
- 3) He/she is below eighteen (18) years of age unless both living parent(s) or legal next-of-kin or legal guardian has consented to such removal; or
- 4) He/she is an incompetent person, unless the living parent(s) or legal next-of-kin or legal guardian has consented to such removal.

SECTION 7. *Opt-Out System.* – Upon the effectivity of this Act, any person who objects to the removal of his/her organ and/or tissue after his death may register his objection, in respect of that organ and/or tissue, with the DOH-PhilNOS at any time or with the following agencies:

- a. Land Transportation Office (LTO) upon driver's license renewal;
- b. Government Services Insurance System (GSIS);
- c. Social Security System (SSS);

- d. Philippine Health Insurance Corporation (PhilHealth);
- e. Commission on Elections (COMELEC); or
- f. Such other department or agency assigned by the PSA.

Such objection shall be registered and recorded real-time in the PODRRS. Upon the receipt of the duly-signed written objection, the concerned agency shall thereafter issue a certification and an opt-out card to the person which shall serve as a proof that his objection was duly registered and recorded.

Provided that, any person who has registered his/her opt-out may cancel his/her registration at any time in the prescribed form, as may be determined by the DOH-PhilNOS, in coordination with the abovementioned agencies. Such cancellation shall be recorded real-time in the PODRRS.

SECTION 8. *Opt-In System.* – Upon the effectivity of this Act, any person who desired to donate his/her organs and/or tissues, may register, in respect of such organ and/or tissue, with the DOH-PhilNOS shall be considered.

SECTION 9. *Allocation of Organs and Tissues.* – In the allocation of any organ and/or tissues retrieved pursuant to this Act, matching and other circumstances, as may be determined by DOH and DOH-PhilNOS shall be considered.

SECTION 10. *Roles and Functions of DOH-PhilNOS.* – In addition to the roles and functions of the DOH-PhilNOS, as provided by official DOH issuances, policies, laws, rules and/or regulations, it shall act as the central coordinating body to ensure that all deceased donors of organs and/or tissues are allocated accordingly to established criteria and such other roles and functions, as may be deemed necessary. Provided that, DOH-PhilNOS shall operate in coordination with OTROs.

SECTION 11. *Hospital Transplant Ethics Committees (HTECs).* – All hospitals and transplant facilities shall establish their own HTECs. HTECs shall monitor and resolve ethical issues that may arise in the process of organ and tissue donation and transplantation.

The functions of the HTECs shall be in accordance with DOH policies and guidelines and shall have its own Standard Operating Procedures (SOPs) based on the recommendations of the National Transplant Ethics Committee (NTEC).

The members of the HTEC shall ensure its independence from political, institutional, professional, and market influence. HTEC members shall undergo basic and continuing training on organ and tissue donation and transplantation.

SECTION 12. *National Transplant Ethics Committee (NTEC).* – The NTEC shall be established under DOH and shall serve as the national oversight of the HTECs on ethical issues regarding organ and tissue donation and transplantation. In addition, the NTEC is tasked to:

- a. Assist in the formulation of national ethical standards and guidelines on organ and tissue transplantation;
- b. Assist in the development of legislation, rules, and regulations regarding organ and tissue donation and transplantation;
- c. Provide opinions, recommendations, and final resolution of cases referred by HTECs;
- d. Assist in the monitoring of hospitals to ensure compliance with ethical standards or guidelines in relation to organ and tissue donation and transplantation;
- e. Foster awareness on ethical health care issues on organ and tissue donation transplantation;
- f. Participate in international discussions and collaborations with similar committees and organizations in the field; and
- g. Perform such other functions as may be deemed necessary by the Secretary of Health.

SECTION 13. *Persons Authorized to Perform the Retrieval and Transplantation of Organs and Tissues.* – The retrieval and transplantation of organ and tissues shall only be performed by transplant surgeons duly accredited and certified by the Philippine Society of Transplant Surgeons. Provided that, the removal of the eye and eye tissues shall be performed only by the Eye Bank Technicians who undergo training in the science of eye banking conducted by an organization duly-accredited

by the DOH. Such trainings shall be in accordance with the accepted international standards of eye banking and shall include, but not limited to, retrieval, processing, storage, and distribution of eye tissue.

SECTION 14. *Transport of Donated Organs and Tissues.* – In order to maintain the quality and integrity of organs and tissues for transplantation, to ensure traceability, and to minimize any potential risk, it is vital that donor organs and tissues and their accompanying blood and tissue samples are packaged, labelled, and transported to the Transplant Facility appropriately, and in a speedy and timely manner.

SECTION 15. *PhilHealth Assistance.* – Organ and tissue transplantation and deceased organ and tissue procurement, under this Act, shall be covered, partially, or in full, by the Philippine Health Insurance Corporation (PhilHealth). Provided that, the assistance given by PhilHealth shall be determined through fair and transparent assessment process.

SECTION 16. *Prohibited Acts.* – The following acts shall be prohibited:

- a. *Selling of Organs and/or Tissues.* To enter into a contract or agreement under which a person agrees, for valuable consideration, whether given or to be given to himself/herself or to another person, the sale or supply of any organ or tissue, whether before or after his/her death or the death of another person, as the case may be;
- b. *Buying of Organs and/or Tissues.* To give or offer to give valuable consideration for the sale or supply of, or for an offer to sell or supply, any organ from the body of another person;
- c. *Performing organ and/or tissue removal and/or transplantation of an unauthorized person.* To remove and/or transplant any organ and/or tissue of a person without an authorized physician;
- d. *Advertising and promoting the buying and selling of organs and/or tissues.* No person shall issue or cause to be issued any advertisement relating to the buying or selling of any organ and/or tissue in the Philippines; and

- e. *Destroying, forging, mutilating, and altering the PODRRS or any related documentation.* To wilfully destroy, forge, mutilate, or make any unauthorized alteration in the PODRRS or any related documentation.

SECTION 17. *Penalties.* – The following penalties are hereby provided:

- a. Any person found guilty of committing any of the acts enumerated in Section 12 (a), (b), and (c) shall suffer the penalty of imprisonment of twenty (20) years and a fine of not less than One million pesos (P1,000,000.00) but not more than Two million pesos (P2,000,000.00)
- b. Any person found guilty of committing any of the acts under Section 12 (d) and (e) shall suffer the penalty of imprisonment of two (2) years and a fine not less than One hundred thousand pesos (P100,000.00) but not more than Five hundred thousand pesos (P500,000.00)

SECTION 18. *Education and Information Campaign.* – To ensure public awareness of the maximum benefits of organ and tissue donation provided in the Act, the DOH, in cooperation with institutions such as the National Kidney and Transplantation Institute (NKTI), civic and non-government health organizations, and other health-related agencies involved in the donation and transplantation of human organs and tissues, as well as the Department of Education (DepEd) and the Commission on Higher Education (CHED) shall undertake public information and education program for this purpose.

The DOH shall ensure that all health professionals, both in government and private sectors, as well as media organizations from print, radio, and television are encouraged to undertake massive public information campaign to emphasize the importance of organ and tissue donation in relation to the opt-out system.

DepEd and CHED shall mandate the inclusion of organ and tissue donation and the opt-out system, for increased awareness, in the school curriculum and in all medical and paramedical related courses, respectively. Moreover, the importance of organ and tissue donation and the opt-out system shall be included in the Health and Sciences subjects in the curriculum of both the elementary and secondary levels as well as in the general education curriculum in the collegiate level. The Secretary of

Health shall coordinate with the Secretary of Education and the Chairperson of CHED for the effective and efficient implementation of this Act.

The DOH shall further endeavour to disseminate massive public information campaign or organ and tissue donation through other means, such as, but not limited to, the internet, social media, and print ads. The DOH shall also provide annual professional training programs and seminars for clinical staff in the management and implementation of this Act, particularly on the deceased organ and/or tissue donation process.

SECTION 19. *Phased Implementation.* – The DOH and DOH-PhilNOS, in coordination with concerned agencies, shall develop strategies and approaches for the phased implementation of this Act which shall initially consist of massive public information campaign through national and local consultations, surveys, impact assessments, training and seminars, print and online advertisements, television and radio advertisements, among others, for the first six (6) months following the effectivity of this Act.

Immediately after the effectivity of this Act, any individual who decides to opt-out from organ and/or tissue donation may do so in accordance to Sec. 7 of this Act. Provided that, six (6) months following the effectivity of this Act, the opt-out system of organ and/or tissue donation shall be fully implemented.

SECTION 20. *Data Management.* – The DOH and DOH-PhilNOS, in coordination with the National Privacy Commission (NPC) and other concerned agencies, shall ensure that all data compiled under this Act shall be strictly confidential through the implementation of appropriate organizational, physical, and technical security measures in accordance to existing laws, rules, and regulations.

SECTION 21. *Implementing Rules and Regulations.* – The DOH and DOH-PhilNOS, in coordination with the concerned departments and agencies, shall within sixty (60) days from the effectivity of this Act, promulgate rules and regulations to faithfully implement the provisions of this Act.

SECTION 22. *Appropriation.* – The amount of One Billion Pesos (P1,000,000,000.00) shall be appropriated for the management and implementation of this Act which shall be included in the General Appropriations Act (GAA).

SECTION 23. *Repealing Clause.* – All laws, decrees, orders, rules and regulations or other issuances or parts thereof inconsistent with the provisions of this Act are hereby repealed or modified accordingly.

SECTION 24. *Separability Clause.* – If any portion or provision of this Act is declared unconstitutional, the remainder of this Act or any provision not affected thereby shall remain in force and effect.

SECTION 25. *Effectivity.* – This Act shall take effect after fifteen (15) days following the completion of its publication either in the *Official Gazette* or in a newspaper of general circulation in the Philippines.

Approved,